ATENT COOPERATION TRE. Y

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

KASSEBAUM, James, Web et al

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202

Date of mailing (day/month/year)

20 April 2001 (20.04.01)

ETATS-UNIS D'AMERIQUE
in its capacity as elected Office

International application No.
PCT/US00/19549

International filing date (day/month/year)
26 July 2000 (26.07.00)

Applicant

Applicant's or agent's file reference
X-11121

Priority date (day/month/year)
12 August 1999 (12.08.99)

1.	The designated Office is hereby notified of its election made:
	X in the demand filed with the International Preliminary Examining Authority on:
	09 February 2001 (09.02.01)
	in a notice effecting later election filed with the International Bureau on:
2.	The election X was
	was not
	made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland Authorized officer

Pascal Piriou

Telephone No.: (41-22) 338.83.38

Facsimile No.: (41-22) 740.14.35



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REC'D 3 1 OCT 2001

INTERNATIONAL PRELIMINARY EXAMINATION REPORT PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference		See Notific	ation of Transmittal of International
X-11121	FOR FURTHER ACTION		Examination Report (Form PCT/IPEA/416)
International application No.	International filing date (day/month)	/year)	Priority date (day/month/year)
PCT/US00/19549	26/07/2000		12/08/1999
International Patent Classification (IPC) or na A61K9/00	tional classification and IPC		
Applicant			
ELI LILLY AND COMPANY et al.			
This international preliminary examinated and is transmitted to the applicant and is transmitted to the applicant and is transmitted.		by this Inte	rnational Preliminary Examining Authority
2. This REPORT consists of a total of	8 sheets, including this cover sh	eet.	
been amended and are the bas	sis for this report and/or sheets co 07 of the Administrative Instructio	ontaining re	n, claims and/or drawings which have ctifications made before this Authority e PCT).
3. This report contains indications rela	ting to the following items:		
I ⊠ Basis of the report			
II Priority			
	pinion with regard to novelty, inve	entive step a	and industrial applicability
IV Lack of unity of inventio			
V 🛛 Reasoned statement ur		ovelty, inve	ntive step or industrial applicability;
VI Certain documents cite	d		
VII 🛛 Certain defects in the in	ternational application		
VIII 🛛 Certain observations on	the international application		
Date of submission of the demand		ompletion of t	

Date of submission of the demand	Date of completion of this report	
09/02/2001	26.10.2001	
Name and mailing address of the international preliminary examining authority: European Patent Office	Authorized officer	JES MIZNON
D-80298 Munich Tel. +49.89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	1	

INTERNATIONAL PRELIMINARY

International application No. PCT/US00/19549

EXAMINATION REPORT - SEPARATE SHEET

Re Section VIII

Certain observations on the international application

- 1. The word "about", particularly when applied to a range, detracts from the general clarity of claims 1 and 11 (Art. 6 PCT).
- 2. The use of brackets in claims 1-3 and 11 should be avoided since it leads to unclarity whether the figures in brackets are optional or compulsory (Art. 6 PCT).
- Claim 11 contains a reference to the description (the Examples). According to 3. Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

PATENT COOPERATION TREATY

From the	
INTERNATIONAL PRELIMINARY	EXAMINING AUTHORITY

To:

NOV 0 7 20p1

DEMETER, John C. **ELI LILLY AND COMPANY** Lilly Corporate Center Indianapolis, Indiana 46285 **ETATS-UNIS D'AMERIQUE**

ELI LILLY & COMPANY PATENT DIVISION

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL PRELIMINARY **EXAMINATION REPORT**

(PCT Rule 71.1)

Date of mailing (day/month/year)

26.10.2001

Applicant's or agent's file reference

X-11121

IMPORTANT NOTIFICATION

International application No. PCT/US00/19549

International filing date (day/month/year) 26/07/2000

Priority date (day/month/year)

12/08/1999

Applicant

ELI LILLY AND COMPANY et al.

- 1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
- 2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
- 3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/

Authorized officer

European Patent Office D-80298 Munich

Hutterer, G

Tel.+49 89 2399-8066

Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's	s or ager	nt's file reference			See Notification of Transmittal of International
X-11121]		FOR FURTHER A	CTION	Preliminary Examination Report (Form PCT/IPEA/416)
Internation	al applic	ation No.	International filing date	(day/month/y	year) Priority date (day/month/year)
PCT/US	00/195	549	26/07/2000		12/08/1999
Internation A61K9/0		t Classification (IPC) or na	tional classification and IP	C	
Applicant ELI LILL	Y AND	COMPANY et al.			
1		ional preliminary exam nitted to the applicant a	•	prepared b	by this International Preliminary Examining Authority
_		RT consists of a total of			
t	een an		sis for this report and/or	sheets con	description, claims and/or drawings which have ntaining rectifications made before this Authority ns under the PCT).
Thes	e anne	xes consist of a total of	2 sheets.		
3. This	report c	ontains indications rela	ting to the following ite	ms:	
1	⊠ (Basis of the report		`	
. 11		Priority			
H	⊠ l	Non-establishment of o	pinion with regard to no	velty, inven	ntive step and industrial applicability
IV		Lack of unity of invention	n		
V		Reasoned statement ur citations and explanation			ovelty, inventive step or industrial applicability;
VI	⊠ (Certain documents cite	ed		i
VII	⊠ (Certain defects in the in	ternational application		
VIII	⊠ (Certain observations or	the international appli	cation	
· .					
Date of sub	mission	of the demand	· · · · · · · · · · · · · · · · · · ·	Date of con	mpletion of this report
09/02/20	01 -			26.10.2001	1
	examini	iddress of the international ng authority:	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	Authorized	officer State of the state of t
)	D-8029	ean Patent Office 98 Munich 9 89 2399 - 0 Tx: 523656	epmu d	Hedegaa	ard, A
	Fax: +	49 89 2399 - 4465		Telephone I	No. +49 89 2399 8644

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/19549

 Basis of the repor 	I.	Basis	of the	repor
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1.	the and	receiving Office in	response to an invitation und	Discation (Heplacement sheets which have been furnished to ler Article 14 are referred to in this report as "originally filed" t contain amendments (Rules 70.16 and 70.17)):
	1-7	,10-16	as originally filed	
	Cla	ims, No.:		
	1-1	1	with telefax of	09/02/2001
2.	lan	guage in which the i	international application was	ed above were available or furnished to this Authority in the filed, unless otherwise indicated under this item. Authority in the following language: , which is:
				ourposes of the international search (under Rule 23.1(b)).
				application (under Rule 48.3(b)).
				purposes of international preliminary examination (under Rule
3.				sequence disclosed in the international application, the it on the basis of the sequence listing:
		contained in the in	ternational application in writt	en form.
		filed together with	the international application i	n computer readable form.
		furnished subsequ	ently to this Authority in writte	en form.
		furnished subsequ	ently to this Authority in comp	outer readable form.
			t the subsequently furnished oplication as filed has been for	written sequence listing does not go beyond the disclosure in irnished.
		The statement that listing has been ful		computer readable form is identical to the written sequence
4.	The	amendments have	resulted in the cancellation of	of:
		the description,	pages:	
		the claims,	Nos.:	
		the drawings,	sheets:	
5.		This report has bee	en established as if (some of) eyond the disclosure as filed	the amendments had not been made, since they have been (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/19549

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6.	Add	ditional observations, if n	ecessa	ry:	
III.	No	n-establishment of opi	nion wit	th regard	d to novelty, inventive step and industrial applicability
1.	The obv	e questions whether the crious), or to be industriall	claimed y applic	inventior able have	on appears to be novel, to involve an inventive step (to be nonventive not been examined in respect of:
		the entire international	applicat	ion.	
	×	claims Nos. 8-10.			
be	caus	se:			
	×				e said claims Nos. 8-10 relate to the following subject matter which ninary examination (<i>specify</i>):
		the description, claims of that no meaningful opin			dicate particular elements below) or said claims Nos. are so unclear med (specify):
		the claims, or said claim could be formed.	ns Nos.	are so ir	inadequately supported by the description that no meaningful opinior
		no international search	report h	as been	n established for the said claims Nos
	and	eaningful international po for amino acid sequence ructions:	relimina listing t	ry exami	nination cannot be carried out due to the failure of the nucleotide ly with the standard provided for in Annex C of the Administrative
		the written form has not	been fu	ırnished (or does not comply with the standard.
		the computer readable f	orm has	s not bee	en furnished or does not comply with the standard.
٧.	Rea cita	soned statement under tions and explanations	r Article suppo	e 35(2) w rting suc	with regard to novelty, inventive step or industrial applicability; ach statement
1.	State	ement			
	Nov	elty (N)	Yes: No:	Claims Claims	
	Inve	ntive step (IS)	Yes: No:	Claims Claims	
	Indu	strial applicability (IA)	Yes:	Claims	1-7,11

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US00/19549

No: Claims

2. Citations and explanations see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted: see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made: see separate sheet

INTERNATIONAL PRELIMINARY

International application No. PCT/US00/19549

EXAMINATION REPORT - SEPARATE SHEET

Re Section III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claims 8-10 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Section V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP-A-0 128 351 D2: EP-A-0 069 269

D1 discloses (see the table on p. 21) a topical ectoparasiticidal formulation comprising 0.2% cypermethrin (compound C) and 1.0% isopropyl myristate (synergist 4).

D2 discloses (see claim 1) topical ectoparasiticidal formulations comprising 0.0001-90 % of the active agent and 10-80% of spreading agent. Example 1 on page 11 of D2 discloses a composition comprising 5% flumethrin (a pyrethroid) and 30.0% isopropyl myristate. On page 6, lines 10-11 of D2 it is disclosed that isopropyl myristate is particular useful as spreading agent.

The subject-matter of claims 1-6 (formulation), 7 (article of manufacture), 8-10 2. (method) and 11 (formulation) is novel (Art. 33(2) PCT) since the combination of the features "about 0.1 to about 25 weight percent of an ectoparasiticide, selected from a spinosyn, or a physiologically acceptable derivative or salt thereof, and cyperpyrethrin" and "from about 25 to about 99.9 weight percent of a C₃-C₆

7. 13.

EXAMINATION REPORT - SEPARATE SHEET

branched alkyl C₁₀-C₂₀ alkanoate spreading agent" has not been disclosed in the available prior art documents.

3. Document D1, which is considered to represent the most relevant state of the art, discloses (cf. above under item 1) a composition from which the subject-matter of claim 1 differs in that it comprises from about 25 to about 99.9 weight percent of the C₃-C₆ branched alkyl C₁₀-C₂₀ alkanoate spreading agent (instead of 1.0% as in D1).

The problem to be solved by the present invention may be regarded as providing insecticidal formulations that can be applied topically to animals and that permit the active ingredient to be better spread over the surface of the skin and/or the hair of the treated animal.

This problem is solved by incorporating from about 25 to about 99.9 weight percent of the spreading agent.

However, the use of 30.0% isopropyl myristate as spreading agent in pyrethroid formulations is known from e.g. D2. The skilled person would therefore regard it as a normal design option to include this feature in the composition described in document D1 in order to solve the problem posed and, thus, to arrive at a composition according to present claim 1. Therefore, the subject-matter of claim 1 does not involve an inventive step (Art. 33(3) PCT).

- 4. The same applies mutatis mutandis to independent claims 7, 8 and 11.
- 5. A positive international preliminary report for the subject-matter of the dependent claims 2-6 and 9-10 can only be established when they refer to independent claims which meet the requirements of the PCT.
- For the assessment of the present claims 8-10 on the question whether they are 6.

industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Section VI

Certain documents cited

Certain published documents (Rule 70.10)

Application No Patent No

Publication date (day/month/year)

Filing date (day/month/year) Priority date (valid claim) (day/month/year)

WO-A-00 29378

25.05.00

15.11.99

17.11.98 29.04.99

Although WO-A-00 29378 does not constitute prior art within the meaning of Rule 64.1(b) PCT, it could become of relevance in the regional phase. No check has been made as to whether the priorities have been validly claimed.

Re Section VII

Certain defects in the international application

- 1. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the documents D1 and D2 is not mentioned in the description, nor are these documents identified therein.
- 4. The description is not in conformity with the claims as required by Rule 5.1(a)(iii) PCT.

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CLAIMS

- 1. A topical ectoparasiticidal formulation comprising: from about 0.1 to about 25 weight percent of an ectoparasiticide, selected from a spinosyn, or a physiologically acceptable derivative or salt thereof, and cyperpyrethrin; from about 25 to about 99.9 weight percent of a (C₃-C₆) branched alkyl (C₁₀-C₂₀) alkanoate spreading agent; and up to about 70 weight percent of a miscibilizing agent compatible with organic solvent systems.
- A formulation of Claim 1 wherein the spreading agent is a (C₃-C₆) branched alkyl (C₁₂-C₁₆) alkanoate.
- 3. A formulation of Claim 2 wherein the (C₃-C₆) branched alkyl (C₁₂-C₁₆) alkanoate is isopropyl myristate.
- 4. A formulation of Claim 1, 2 or 3 wherein the miscibilizing agent is selected from formic, acetic, propionic, benzoic, butyric, valeric, caproic, enanthic, caprylic, pelargonic, capric, undecylic, lauric, tridecylic, myristic, pentadecylic, palmitic, margaric, stearic, oleic, arachidic, behenic, lignoceric, cerotic, montanic, triacontanoic, psyllic, or ceroplastic acids.
- 5. A formulation of Claim 1, 2, 3 or 4, which further comprises a miscibilizing agent selected from benzyl alcohol, ethylene glycol phenyl ether, D-timonene, N-methyl-2-pyrrolidinone, methylated soybean oils and soybean oil methyl esters.
- 6. A formulation of Claim 1, 2, 3, 4 or 5 which further comprises an effective amount of an antimicrobial agent.
- 7. An article of manufacture, comprising packaging material and contained within said packaging material a topical formulation for controlling an ectoparasite infestation on a small ruminant or companion animal, wherein said formulation comprises
- a topical unit dose of a formulation of Claim 1, 2, 3, 4, 5 or 6; and, wherein said packaging material comprises a label or package insert with instructions for topically administering the dose to the animal.
- 8. A method of controlling an ectoparasite infestation on a small ruminant or companion animal, comprising topically applying to the hair and/or skin

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-18-

of the animal a formulation of Claim 1, 2, 3, 4, 5 or 6.

- The method of Claim 8 wherein the formulation is applied using a spot-on protocol.
- 10. The method of Claim 8 wherein the formulation is applied using a pour-on protocol.
- 11. A topical ectoparasiticidal formulation comprising from about 0.1 to about 25 weight percent of an ectoparasiticide, selected from spinosyn or a physiologically acceptable derivative or salt thereof, and cyperpyrethrin, from about 25 to about 99.9 weight percent of a (C₃-C₆) branched alkyl (C₁₀-C₂₀) alkanoate spreading agent, and up to about 70 weight percent of a miscibilizing agent compatible with organic solvent systems, substantially as hereinbefore described with reference to any one of the Examples.

DODGO2 NJH 319544v1



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INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference	FOR FURTHER see Notification of (Form PCT/ISA/2	of Transmittal of International Search Report (20) as well as, where applicable, item 5 below.
X-11121 International application No.	International filing date (day/month/year)	(Earliest) Priority Date (day/month/year)
PCT/US 00/19549	26/07/2000	12/08/1999
Applicant		
ELI LILLY AND COMPANY		
This International Search Report has been according to Article 18. A copy is being tra	n prepared by this International Searching Aut ansmitted to the International Bureau.	hority and is transmitted to the applicant
	of a total of4 sheets. a copy of each prior art document cited in this	report.
1. Basis of the report	the second secon	ois of the international application in the
a. With regard to the language, the language in which it was filed, unl	international search was carried out on the ba ess otherwise indicated under this item.	ыз от те тетанопатаррисаноп пт те
the international search w Authority (Rule 23.1(b)).	ras carried out on the basis of a translation of	the international application furnished to this
b. With regard to any nucleotide an was carried out on the basis of th	Id/or amino acid sequence disclosed in the interest of the sequence listing: In a polication in written form.	nternational application, the international search
. –	ernational application in computer readable for	m.
furnished subsequently to	this Authority in written form.	
· · · · · · · · · · · · · · · · · · ·	this Authority in computer readble form.	
the statement that the sul international application a	osequently furnished written sequence listing one is the sequence listing of t	does not go beyond the disclosure in the
the statement that the infe furnished	ormation recorded in computer readable form	is identical to the written sequence listing has been
2. X Certain claims were fou	nd unsearchable (See Box I).	
3. Unity of invention is lac	king (see Box II).	
4. With regard to the title ,		
	ubmitted by the applicant.	
the text has been establis	shed by this Authority to read as follows:	
5. With regard to the abstract ,	÷	
	ubmitted by the applicant.	
the text has been establis within one month from th	shed, according to Rule 38.2(b), by this Author e date of mailing of this international search re	rity as it appears in Box III. The applicant may, aport, submit comments to this Authority.
6. The figure of the drawings to be pub	lished with the abstract is Figure No.	
as suggested by the app	licant.	None of the figures.
because the applicant fai	led to suggest a figure.	
because this figure bette	r characterizes the invention.	

INTERNATIONAL SEARCH REPORT

A. CLASSIFICATION OF SUBJECT MATTER IPC 7 A61K9/00

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

CHEM ABS Data, EPO-Internal

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Х	EP 0 128 351 A (BAYER) 19 December 1984 (1984-12-19) claims 4,6 page 23; example 3 page 25; example 9	1-3,5, 9-13
X	EP 0 069 269 A (BAYER) 12 January 1983 (1983-01-12) claim 1 page 5, line 5 -page 7, line 15 page 11; example 1/	1-3,6,7, 9-13

X Further documents are listed in the continuation of box C.	Patent family members are listed in annex.	
 Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier document but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed 	 *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art. *&* document member of the same patent family 	
Date of the actual completion of the international search	Date of mailing of the international search report	
21 November 2000	07/12/2000	
Name and mailing address of the ISA	Authorized officer	
European Patent Office, P.B. 5818 Patentlaan 2 NL – 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ventura Amat, A	

INTERNATIONAL SEARCH REPORT

	tion) DOCUMENTS CONSIDERED TO BE RELEVANT	Relevant to claim No.
ategory °	Citation of document, with indication, where appropriate, of the relevant passages	neievani to ciaim no.
X	DATABASE WPI Week 198721 Derwent Publications Ltd., London, GB; AN 1987-145349 XP002153469 & HU 41 238 A (NEHEZVEGYIPARI), 28 April 1987 (1987-04-28) abstract	1-3,9-13
X	CHEMICAL ABSTRACTS, vol. 102, no. 3, 21 January 1985 (1985-01-21) Columbus, Ohio, US; abstract no. 19640, KIERAN, PETER JOHN ET AL: "Pour-on formulation for lice control" XP002153466 abstract & AU 83219 47 A (WELLCOME AUSTRALIA LTD., AUSTRALIA) 12 April 1984 (1984-04-12)	1-3,5, 9-13
X .	CHEMICAL ABSTRACTS, vol. 101, no. 11, 10 September 1984 (1984-09-10) Columbus, Ohio, US; abstract no. 85712, KIERAN, PETER JOHN ET AL: "Pyrethroids for combatting sheep ectoparasites" XP002153467 abstract & AU 82918 50 A (WELLCOME AUSTRALIA LTD., AUSTRALIA) 24 March 1983 (1983-03-24)	1-3,5, 9-13
X	CHEMICAL ABSTRACTS, vol. 100, no. 7, 13 February 1984 (1984-02-13) Columbus, Ohio, US; abstract no. 47094, KIERAN, PETER JOHN ET AL: "Control of sheep lice" XP002153468 abstract & AU 81770 04 A (WELLCOME AUSTRALIA LTD., AUSTRALIA) 27 May 1982 (1982-05-27)	1-3,5, 9-12
P,X	WO 00 29378 A (NOVARTIS) 25 May 2000 (2000-05-25) claims 22,25 page 11, paragraph 7 -page 15, paragraph 1 page 82; example 5	1-13

2

INTERNATIONAL SEARCH REPORT It ation on patent family members

national Application No rcT/US 00/19549

Patent document cited in search repor	t	Publication date	Patent family member(s)	Publication date
EP 128351	A	19-12-1984	DE 3317823 A AU 2806384 A DK 241184 A GR 82066 A HU 34721 A JP 59212403 A PH 19050 A ZA 8403680 A	22-11-1984 22-11-1984 18-11-1984 13-12-1984 28-04-1985 01-12-1984 11-12-1985 24-12-1984
EP 69269	A	12-01-1983	DE 3125897 A AT 21478 T AU 560431 B AU 8546682 A DE 3272717 D DK 294882 A JP 1013681 B JP 58008002 A NZ 201086 A PH 18948 A ZA 8204663 A	10-02-1983 15-09-1986 09-04-1987 06-01-1983 25-09-1986 02-01-1983 07-03-1989 18-01-1983 11-04-1986 14-11-1985 27-04-1983
HU 41238	Α	28-04-1987	NONE	
AU 8321947	Α		NONE	
AU 8291850	Α		NONE	
AU 8177004	Α		NONE	
WO 0029378	Α	25-05-2000	AU 1553100 A	05-06-2000

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APTICLE 34

<u>CLAIMS</u>

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- A topical ectoparasiticidal formulation comprising: from about 1. 0.1 to about 25 weight percent of an ectoparasiticide, selected from a spinosyn, or a physiologically acceptable derivative or salt thereof, and cyperpyrethrin; from about 25 to about 99.9 weight percent of a (C3-C6) branched alkyl (C10-C20) alkanoate spreading agent; and up to about 70 weight percent of a miscibilizing agent compatible with organic solvent systems.
 - A formulation of Claim 1 wherein the spreading agent is a (C3-2. C₆) branched alkyl (C₁₂-C₁₆) alkanoate.
 - A formulation of Claim 2 wherein the (C3-C6) branched alkyl 3. (C₁₂-C₁₆) alkanoate is isopropyl myristate.
 - A formulation of Claim 1, 2 or 3 wherein the miscibilizing agent is selected from formic, acetic, propionic, benzoic, butyric, valeric, caproic, enanthic, caprylic, pelargonic, capric, undecylic, lauric, tridecylic, myristic, pentadecylic, palmitic, margaric, stearic, oleic, arachidic, behenic, lignoceric, cerotic, montanic, triacontanoic, psyllic, or ceroplastic acids.
 - 5. A formulation of Claim 1, 2, 3 or 4, which further comprises a miscibilizing agent selected from benzyl alcohol, ethylene glycol phenyl ether, Dlimonene, N-methyl-2-pyrrolidinone, methylated soybean oils and soybean oil methyl esters.
 - б. A formulation of Claim 1, 2, 3, 4 or 5 which further comprises an effective amount of an antimicrobial agent.
- 7. An article of manufacture, comprising packaging material and contained within said packaging material a topical formulation for controlling an ectoparasite infestation on a small uminant or companion animal, wherein said formulation comprises

a topical unit dose of a formulation of Claim 1, 2, 3, 4, 5 or 6; and, wherein said packaging material comprises a label or package insert with instructions for topically administering the dose to the animal.

8. A method of controlling an ectoparasite infestation on a small ruminant or companion animal, comprising topically applying to the hair and/or skin 009487497/45800/19549

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of the animal a formulation of Claim 1, 2, 3, 4, 5 or 6.

- The method of Claim 8 wherein the formulation is applied using a spot-on protocol.
- 10. The method of Claim 8 wherein the formulation is applied using a pour-on protocol.
- 11. A topical ectoparasiticidal formulation comprising from about 0.1 to about 25 weight percent of an ectoparasiticide, selected from spinosyn or a physiologically acceptable derivative or salt thereof, and cyperpyrethrin, from about 25 to about 99.9 weight percent of a (C₃-C₆) branched alkyl (C₁₀-C₂₀) alkanoate spreading agent, and up to about 70 weight percent of a miscibilizing agent compatible with organic solvent systems, substantially as hereinbefore described with reference to any one of the Examples.

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